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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,168	09/25/2003	Gil M. Vardi	S63.2H-12012-US01	2222
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MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			EXAMINER HOUSTON, ELIZABETH	
			ART UNIT 3731	PAPER NUMBER
			MAIL DATE 09/18/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/670,168

Applicant(s)

VARDI ET AL.

Examiner

Elizabeth Houston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8,13-17 and 19-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8,13-17 and 19-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Priority

1. For the record, claims 4, 7, 17 and 22 claim subject matter that does not have support in the parent case (09/860,744), therefore they will not receive the benefit of the earlier filing date.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "22" has been used in figure 2 to designate both "inflation tube" and "inflation lumen". It is unclear in the drawing what designates the outline of the distal portion of the inflation tube. For example is applicant intending to show that the distal shaft is connected to the inflation tube only at the bond portion and therefore there is an open space between the distal shaft and inflation tube where the bond portion is? Or, is the line designating the outline distal shaft also designating the outline of the inflation tube? In other words is the second line from the top indicating the inflation tube as it seems from the extension of the proximal portion of the inflation tube, or is the third line indicating the inflation tube? Further, if it is the second line that indicates the outline of the distal shaft and the outline of the inflation tube, why would the bond area be on the inside of the inflation tube? Additionally, are figures 2 and 4 supposed to be representing the same embodiment? The drawings seem to indicate that they are different embodiments in terms of where the guidewire ports are located, however the specification does not indicate so. Clarification is requested. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid

abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claim 16 is objected to for the following reason: Claim 16 recites the limitation "said first lumen" and the limitation "said second lumen". There is insufficient antecedent basis for this limitation in the claim.
3. Claim 17 is objected to for the following reason: Claim 17 recites the limitation "said second lumen". There is insufficient antecedent basis for this limitation in the claim.
4. Claim 21 is objected to for the following reasons: Use of the word "distance" in the claim is unclear. A distance indicates an amount of space between two things, which is not applicable in this case since there is no reference point from where or to where the distance is being measured.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim recites that the "first distance is between 50 and 150 centimeter". According to claim the first distance refers to the main exit port. The specification states at the top of page 5 that alternatively the second distance (branch exit port) can be between 50 and 150 cm, but does not state that the first distance can be between 50 and 150 cm.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

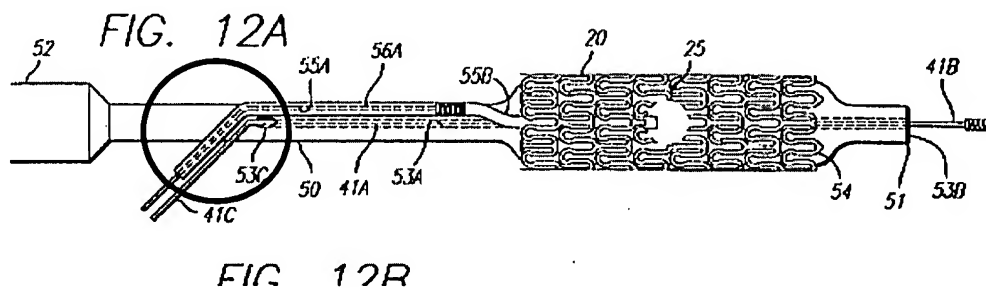
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4, 13-19 and 21-22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wilson (EP 0 897 700).
8. Wilson discloses catheter system for positioning a stent at a vessel bifurcation substantially as claimed (see entire document). Specifically, Wilson discloses a catheter

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(Fig 12a-c) comprising a channel (53a) having a main guidewire lumen extending from a distal end (51) to a main exit port (53c) located at a first distance. There is a branch guidewire enclosure (55a) extending proximally from a side opening (25) of a stent (20) to a branch exit port (see for example 56c) located at a second distance. The branch guidewire enclosure is coupled to the channel adjacent (or near, close to) the branch exit port. The first and second distances of the exit ports are less than a distance from the proximal end to the distal end of the catheter and greater than a distance from the distal end of the catheter to the proximal end of the stent. The device has a balloon (54) and an inflation portion for inflating the balloon. The catheter comprises a bond portion (indicated by circle - see below) that connects the main exit port, the branch exit port and a proximal tube.



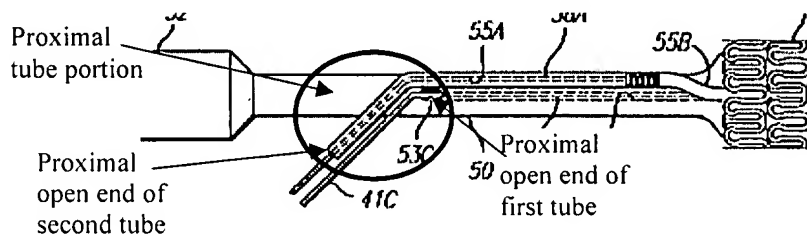
9. Regarding the limitation "said first distance and said second distance being *substantially* equal"; the use of language such as "substantially" is terminology of a relative degree and merely requires that the prior art show the distances being close to equal.

10. Alternatively, should applicant disagree with examiner's interpretation of the terminology "substantially", examiner asserts that would be obvious to one having ordinary skill in the art at the time of the invention to vary the size of the branch guide

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wire tube (thereby changing the distance of the branch exit port) in order to produce a catheter with a more streamline profile for ease of delivery. Further, it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch* 617 F.2d 272,205 USPQ 215 (CCPA 1980).

11. Regarding claim 13, Wilson discloses a catheter with a proximal tube *portion* and a distal *portion* comprising a first tube (53A) with a proximal open end (53C) and a second tube (55A) with a proximal open end (for example 56C). There is a bond *portion* that connects that proximal tube *portion* with the distal *portion*. The bond portion has a three-way bond that couples the proximal tube portion to the proximal open end of the first tube and the proximal open end of the second tube.



12. The first/main guidewire lumen/tube is attached to the branch/second lumen/tube external of the bond portion. The bond portion is located at a predetermined distance proximally from a proximal portion of the stent. The proximal tube portion connects to the bond at a distance from where the distal portion connects to the bond. The first and second guide wires exit at the bond portion.

Claim Rejections - 35 USC § 103

13. Claims 5, 8, 17, 20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson.

14. Wilson discloses the claimed invention as stated above except for the dimensions locating the exit openings and the length of the guidewire and the attachment along the entire length of the second lumen/tube. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary the size of the catheter and therefore the location of the exit ports depending on the size and location of the lumen in which it would be used. For instance catheter used on an infant would be significantly smaller than that used on a large adult. Additionally, a catheter that is being delivered to the aorta will be larger than one that is being delivered to the brain. Such a modification would have involved a mere change in the size of a component, and a change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

15. Regarding claim 17, it would be obvious to one having ordinary skill in the art at the time of the invention to vary the length of the branch guide wire tube in order to produce a catheter with a more streamline profile for ease of delivery. The modified catheter would result in one where the attachment of the first and second tube is along an entire length of the second tube.

Response to Arguments

16. Applicant's arguments filed 07/02/07 have been fully considered but they are not persuasive. Applicant's argument that Wilson does not disclose a main exit port and a branch exit port extending substantially equal distances from the distal end of the catheter is based on an unsubstantiated interpretation of the prior art. Applicant

indicates that the open end (near 56C) of the guidewire lumen 55A appears to be outside the body since Wilson states that the guidewire (56A) is advanced by the physician pushing the proximal end (56C) from outside the body. Applicant's attention is drawn to the fact that the proximal end of the **guidewire** (56C) is pushed from outside the body, not the proximal end of the guidewire lumen (55). Although 56C points to the proximal end of the guidewire lumen, the specification makes all reference to 56C as the proximal end of the guidewire. Thus, it is not explicitly stated that the proximal opening of the guidewire lumen is outside of the body, as applicant asserts.

17. As stated above, regarding the limitations "substantially equal", examiner asserts that the terminology "substantially" is open to broad interpretation and does not require that the distances be exactly equal, but merely close to equal.

18. Regarding applicant's arguments that "Wilson does not disclose a branch guidewire enclosure coupled to a channel adjacent a branch exit port", examiner respectfully disagrees. The term "adjacent" merely requires the branch guidewire enclosure be coupled to the channel "near" or "close to" the branch exit port. Examiner asserts that Wilson does in fact teach this limitation.

19. Although examiner inadvertently omitted claim 7 from the 102 rejection statement, examiner points out that the claim was addressed in the body of the rejection.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

eh


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

9/12/07.